



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,824	05/14/2001	Kristin J. Godbey	56466US002	9149
32692	7590	01/07/2010		
3M INNOVATIVE PROPERTIES COMPANY				
PO BOX 33427				
ST. PAUL, MN 55133-3427				
EXAMINER				
AHMED, HASAN SYED				
ART UNIT		PAPER NUMBER		
1615				
NOTIFICATION DATE		DELIVERY MODE		
01/07/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com

LegalDocketing@mmm.com

Office Action Summary

Application No.

09/854,824

Applicant(s)

GODBEY ET AL.

Examiner

HASAN S. AHMED

Art Unit

1615

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Paper No(s)/Mail Date 2/25/06

DETAILED ACTION

Receipt is acknowledged of applicants' amendment and remarks, filed on 18 September 2009.

* * * * *

Information Disclosure Statement

An examiner initialed Form PTO-1449 submitted with the Information Disclosure Statement filed on 25 February 2008 is attached to this Office action.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-5 and 7-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,780,047 ("Kamiya") in view of U.S. Patent No. 4,855,142 ("Fankhauser").

Kamiya discloses a device for delivering at least one active agent to a localized body surface (see col. 1, lines 4-12) comprising:

- the cold water-soluble carrier of instant claim 1 (see col. 2, lines 14-49);
- the cold water-soluble adhesive of instant claim 1 (see col. 4, line 36);
- the support layer of instant claim 1 (see col. 10, line 44);
- the nonwoven fabric of instant claim 2 (see col. 6, line 2);

Art Unit: 1615

- the monomers of instant claim 3 (*see* col. 4, line 12);
- the polyvinyl alcohol of instant claim 4 (*see* col. 3, lines 7-8);
- the gelatin of instant claim 5 (*see* col. 4, line 41);
- the alkyl ether ethoxylate (phenylethyl alcohol) of instant claim 8 (*see* col. 7, line 35);
- the pressure sensitive adhesive of instant claim 10 (*see* col. 10, lines 30-43);
- the cold water-soluble polymer of instant claim 11 (*see* col. 3, lines 7-8);
- the plasticizer (sorbitol) of instant claim 11 (*see* col. 5, line 11);
- the water-soluble monomer of instant claim 12 (*see* col. 4, line 12);
- the polysaccharide of instant claim 13 (*see* col. 3, line 24);
- the polymeric film of instant claim 14 (*see* col. 6, lines 35-44);
- the cold water-soluble carrier of instant claim 15 (*see* col. 2, lines 14-49);
- the cold water-soluble adhesive of instant claim 15 (*see* col. 4, line 36);
- the support layer of instant claim 15 (*see* col. 10, line 44);
- the active agent effective for treatment of skin of instant claim 16 (*see* col. 1, line 7);
- the dye of instant claim 17 (*see* col. 7, line 54);
- the sodium monophosphate (sodium phosphate) of instant claim 18 (*see* col. 7, line 7);
- the appliqué (pigment) of instant claim 19 (*see* claim 11);
- the perfume of instant claim 20 (*see* claim 11);
- the deodorant (perfume) of instant claim 21 (*see* claim 11);

Art Unit: 1615

- the drug of instant claims 22, 23, and 25 (*see* col. 7, line 16);
- the nonwoven fabric of instant claim 29 (*see* col. 6, line 2);
- the monomers of instant claim 30 (*see* col. 4, line 12);
- the polyvinyl alcohol of instant claim 31 (*see* col. 3, lines 7-8);
- the monohydric alcohol (phenylethyl alcohol) of instant claim 32 (*see* col. 7, line 35);
- the alkyl ether ethoxylate (phenylethyl alcohol) of instant claim 33 (*see* col. 7, line 35);
- the pressure sensitive adhesive of instant claim 35 (*see* col. 10, lines 30-43);
- the cold water-soluble polymer of instant claim 36 (*see* col. 3, lines 7-8);
- the plasticizer (sorbitol) of instant claim 36 (*see* col. 5, line 11);
- the water-soluble monomer of instant claim 37 (*see* col. 4, line 12);
- the polysaccharide of instant claim 38 (*see* col. 3, line 24);
- the polymeric film of instant claim 39 (*see* col. 5, line 40).

The coating, dissolving, suspending, and emulsifying processes of claims 24, 25, 27, and 28 are not essential to a determination of patentability of the system disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Kamiya explains that the disclosed device is beneficial because it, "...can exert excellent effects of relieving topical symptoms of a human body." See col. 2, lines 15-16.

Kamiya differs from the instant application in that it does not teach a carrier comprising a plasticizer.

Fankhauser teaches a pharmaceutical plaster consisting of two discrete layers comprising (a) a cover film and (b) an adhesive layer (see col. 2, lines 5-8). The cover film (reading on the carrier of instant claims 1 and 15) consists of a polyvinyl alcohol (reading on the polymer of instant claims 1 and 15) and a plasticizer (see col. 2, lines 9-12). The plasticizer may be glycerin (see Example 1, col. 6, line 53). Fankhauser does not teach a releasable support layer, however use of a support layer in combination with two water-soluble layers is taught by Kamiya (see col. 6, lines 35-44).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a device for delivering at least one active agent to a localized body surface comprising a cold water-soluble carrier (further comprising a polymer and a plasticizer), a cold water soluble adhesive, and a support layer, as taught by Kamiya in view of Fankhauser. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a device because it can relieve topical symptoms of a human body, as explained by Kamiya (see above).

*

2. Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,780,047 ("Kamiya") in view of U.S. Patent No. 4,855,142 ("Fankhauser") further in view of U.S. Patent No. 5,028,435 ("Katz").

Kamiya and Fankhauser are discussed above.

Kamiya explains that the disclosed device is beneficial because it, "...can exert excellent effects of relieving topical symptoms of a human body." *See* col. 2, lines 15-16.

The Kamiya reference differs from the instant case in that it does not teach the arabinogalactan of instant claim 6.

Katz, et. al. teach use of a protein and a carbohydrate in a transdermal system.

Katz, et. al. disclose a transdermal delivery system comprising a backing having a matrix layer which incorporates a drug and a percutaneous enhancer for the drug. At least one of the drug and enhancer is contained within a plurality of polymeric particles dispersed throughout the matrix layer (*see* col. 3, lines 58-62). The particles may be formed using natural polymers such as arabinogalactan (*see* col. 7, lines 28-32).

Katz, et. al. explain that polymers such as arabinogalactan and gelatin are useful because they contribute to the stability of the transdermal drug delivery device, as well as to a long shelf life for the device (*see* col. 7, lines 14-19).

Thus, it would have been obvious for one of ordinary skill in the art at the time of the invention to add a protein, such as collagen, and a carbohydrate, such as arabinogalactan to a transdermal delivery device, as taught by Kamiya in view of Katz,

et. al. Motivation to do so, as explained above, would come from increased stability and longer self life of the device.

* * * * *

Response to Arguments

Applicants' arguments filed on 18 September 2009 have been fully considered but are not persuasive.

Applicants argue that Kamiya does not disclose a device with a construction of 1) support layer, 2) carrier, and 3) adhesive. See remarks, pages 9-10.

As explained in the 35 USC 103 rejection above, Fankhauser teaches a carrier film and an adhesive. Fankhauser does not teach a releasable support layer, however, use of a releasable support layer with two water-soluble layers is taught by Kamiya (see col. 6, lines 35-44).

* * * * *

Conclusion

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 1615

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

★

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615